IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No. 7166
Robert Chow et al.	Examiner: Anoop Singh
Application No.: 09/998,832	Technology Center/Art Unit: 1632
Filed: November 29, 2001	DECLARATION OF DR. ROBERT CHOW AND DR. LAWRENCE PETZ UNDER 37 C.F.R. §1.132
For: STEM CELL SCREENING AND TRANSPLANTATION THERAPY FOR HIV INFECTION	
Customer No.: 20350	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Robert Chow and Lawrence Petz, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of our own knowledge are true, and statements made on information or belief are believed to be true and correct.

2. I, Dr. Robert Chow, am currently Vice Chairman and Global/Chief Medical Director at StemCyte, Inc. I received my Bachelor of Arts from Rutgers College in 1983. I received my M.D. from Harvard Medical School in 1995 and my Masters degree (A.M.) in Cell & Developmental Biology from Harvard University in 1994. I was a Resident and Fellow in Clinical and Anatomic Pathology at UCLA Medical Center in Los Angeles CA. I founded StemCyte, Inc. in 1997 and served as its Chairman from 1997 to 2003. Currently, I also serve on the Executive Committee and Cord Blood Committee of the National Marrow Donor

EXHIBIT A

Program as an *ex officio* member. A copy of my curriculum vitae is attached hereto as Exhibit D.

3. I, Dr. Lawrence D. Petz, am currently Chief Medical Officer and Medical Director at StemCyte, Inc. I received my Bachelor of Science from University of Illinois in 1953. I received my M.D. from University of Illinois College of Medicine in 1955. Between 1956 and 1963, I was a Resident in Medicine at Cook County Hospital, San Francisco General Hospital & San Francisco VA Hospital and Fellow in Hematology at Hammersmith Hospital and Royal Postgraduate Medical School. I was Chairman of Division of Medicine at City of Hope National Medical Center, California between 1981 and 1985 and was Professor of Pathology & Laboratory Medicine and Director of Transfusion Medicine at UCLA from 1987 to 2000. I have chaired the Cord Blood Forum since its inception and organized the 1st, 2nd, 3rd & 4th Annual International Cord Blood Transplantation Symposium. Along with Professor Karl Blume of Stanford University, we edited the 1st Bone Marrow Transplantation Textbook in the world in 1983. A copy of my curriculum vitae is attached hereto as Exhibit E

4. The present invention is a method of treating or preventing an HIV infection caused by a macrophage tropic strain of HIV by transplantation of umbilical cord blood as a stem cell rich population of cells into an appropriate patient.

5. We have read and are familiar with the contents of this patent application. In addition, we have read an Office Action and references cited therein, dated January 17, 2006, received in the present case. It is our understanding that the Examiner is concerned that the specification does not provide enablement of the full breadth of claimed invention. Specifically, the Examiner states that the specification does not provide enablement for one of skill to make and use an invention commensurate in scope with those claims, *i.e.*, methods to prevent or treat HIV by transplanting a stem-cell rich population of cells that carry a beneficial gene into the HIV patient. The Office Action also alleges that undue experimentation is required to practice the claimed invention.

6. This declaration is provided to demonstrate that the specification teaches full use of the claimed methods. In particular, the specification in combination with the knowledge in the art at the time of filing provide sufficient guidance to allow one of skill to use the claimed methods to obtain umbilical cord blood samples, *i.e.*, a stem cell source, from individuals that have a beneficial gene and to transplant the umbilical cord cells into an appropriate patient for treatment or prevention of HIV, in particular a macrophage tropic strain of HIV.

7. At the time of filing the application, transplantation of umbilical cord blood into patients to reconstitute the patient's immune system was routine. A number of diseases were treated using umbilical cord blood transplantation, including, *e.g.*, malignancies and benign genetic blood disorders. Briefly, after a patient had been identified as a recipient of an umbilical cord blood transplant, the patient's own immune system was reduced or eliminated using, *e.g.*, radiation or chemotherapy. Umbilical cord blood was then administered to the patient. Umbilical cord blood contains stem cells which eventually produced sufficient progeny in the patient to reconstitute an immune system for the patient.

7. The dosage of umbilical cord blood stem cells is based on the size of the recipient patient. For umbilical cord blood samples, either total nucleated cells or CD34+ cells can be counted and used as a surrogate for the stem cells that will eventually repopulate the patient's immune system. Typical dosages of umbilical cord blood are 2×10^7 nucleated cells/kg patient weight or 1.0×10^5 CD34+ cells/kg patient weight. Typical cell number dosages of *e.g.*, peripheral blood or bone marrow sources of stem cells, are ten-fold greater than umbilical cord blood dosages.

9. A unit of umbilical cord blood, *i.e.*, the amount taken from one donor, is usually sufficient to transplant most pediatric and adult patients. Larger patients can be transplanted with two units that have appropriate markers and beneficial genes. The dosage of umbilical cord blood stem cells is usually not varied depending on the disease. Because one or at most two units or umbilical cord blood will be sufficient to transplant most patients, *ex vivo* or *in*

vivo expansion of stem cells from umbilical cord blood is not required to perform the claimed methods.

10. In view of the foregoing, it is our scientific opinion that one of skill in the art would recognize how to treat or prevent infection by a macrophage tropic HIV strain by transplantation of umbilical cord blood cells that contain a beneficial gene into an appropriate patient based on the information disclosed in the specification, as well as information in the art at the time of filing. In addition, it is our scientific opinion that any experimentation required by those of skill to perform these methods would be routine. The specification, therefore, enables the invention.

Date: 7/17/06 By: Robert Chow, M.D.

Date: 7/17/06 By: Lawrence D. Petz, M.D.
Lawrence D Petz, M.D.

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